DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MD 21702-5012

REPLY TO
ATTENTION OF

MCMR-ZB-QM

2 MAR 2005

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Command Policy 2005-01, USAMRMC Requirement for Audits in the FDA Regulated Environment

1. References.

a. 21 CFR Part 56.115 IRB Records.

b. 21 CFR Part 58 – Good Laboratory Practice.

c. 21 CFR Parts 312.56 Review of ongoing investigations.

d. International Conference on Harmonization, Good Clinical Practice: Consolidated Guidance (ICH-E6), April 1996, Section 5.19.

e. 21 CFR Parts 210 – Current Good Manufacturing Practices in Manufacturing, Processing, Packing or Handling of Drugs in General

2. Purpose. This memorandum establishes the US Army Medical Research and Materiel Command (USAMRMC) policy that identifies the requirement that USAMRMC must conduct audits on its ongoing effort in the development of medical devices, pharmaceuticals, biologics, and vaccines to meet its regulatory requirements.

3. Background.

a. The purpose of USAMRMC research and development activities is to provide The Food and Drug Administration (FDA) approved pharmaceuticals and devices or licensed biologics to members of the United States military. These activities are governed by Federal, DOD, and Army regulations and they result in submissions to the FDA for eventual approval or licensure. Those research and development activities are subject to the compliance requirements of the FDA. The FDA has the duty to ensure product safety, efficacy, and purity. The FDA accomplishes this duty in part through their oversight inspection or audit program. Therefore, the Command must have in place as part of its Quality efforts a compliance program to ensure that the FDA-regulated activities within the Command will meet FDA standards.

b. Audits are one aspect of a compliance program. Audits are systematic and independent investigative examinations of activities to determine the adequacy of and adherence to established procedures, instructions, specifications, codes, and standards or other applicable contractual and licensing requirements and the effectiveness of implementation. The requirements defined in The Food, Drug, and Cosmetic Act; Title 21, Code of Federal Regulations; policy manuals; SOPs; study protocols; batch production records; and other regulatory documents both internal and external to the organizations shall form the basis of the audits.

4. Applicability and Scope. This policy is applicable to USAMRMC, its subordinate commands and activities, and research and development activities supported by USAMRMC resources in which The Army Surgeon General (TSG) is the Sponsor of an Investigational New Drug (IND) application, an Investigational Device Exemption (IDE) or New Drug Application (NDA), a pre-Market Notification (510k), a Product Marketing Application (PMA), or a Biologics License Application (BLA).

5. Policy.

a. The USAMRMC Headquarters Quality Management Office (QMO) will be responsible for developing policy and standards and providing oversight to the audit function of the command. As the Sponsor's quality proponent the QMO will have the authority to audit FDA-regulated activities conducted by the Command or under the auspices of a TSG-sponsored IND, IDE, NDA, 510k, PMA, or BLA. As the Sponsor's Quality Unit the QMO will be responsible for the clinical quality audit function as required in the ICH E6 guideline for clinical research studies.

b. A USAMRMC Subordinate Command (SC) that has an established Quality Unit (QU) will be responsible for the conduct of an audit program internal to their organization. Management of the audit program will reside within the SC with oversight from the QMO.

c. An audit will be performed when deemed necessary by the QMO and will be based on the significance of the process/product as it relates to the product IND or IDE status, product approval/licensure maintenance requirements, or the sensitivity accorded the regulated activity based on outside interest/scrutiny or internal interest.

d. The QMO or SC QU will perform the audit and report verbally the results of the audit to the commander of the audited organization. A formal report will be written to document the audit outcome. Written audit reports will be submitted to the commander of the audited organization within 20 business days after the audit is conducted. The audit reports generated by the QMO will be distributed to the audited organization, the

Sponsor's Representative, SC Commander, and USAMRMC Commander. Written audit reports generated by a SC QU will be distributed to the SC Commander.

e. Audit reports will have the following disclaimer located in the footer on each page of the report; "Quality Assurance Document under 10 USC 1102. Copies of this document, enclosures thereto, and information there from will not be further released under penalty of the law. Unauthorized disclosure carries a statutory penalty of not more than $3,000 in the case of a first offense and not more than $20,000 in the case of subsequent offense." The QMO or SC QU will distribute the report to those listed on the report. Requests for additional reports to be sent to those not listed on the report should be made to the QMO or SC QU so that there is documented distribution.

f. The original audit report will go to the addressee and a copy will be maintained by the QMO or SC QU conducting the audit in a format that facilitates appropriate dissemination yet maintains confidentiality from unauthorized access. The time period for maintenance of the audit report will vary depending on the subject of the audit, but in no case will be destroyed prior to approval/licensure of product or decision to no longer pursue approval/licensure. In the latter case the audit report may be destroyed two years after decision is made to no longer pursue FDA approval/licensure.

g. Response by the auditee to the audit observations will be addressed in a Corrective Action Plan which will identify appropriate remediation plans and timeline to address the identified observation. The Plan will be forwarded to the appropriate auditing organization for review and follow-up purposes.

6. This policy will continue in effect until rescinded or superceded.

LESTER MARTINEZ-LOPEZ
Major General, MC
Commanding

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